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TITLE: The Effect of Prosthetic Socket Interface Design on Socket Comfort, Residual Limb Health, and Function for the Transfemoral Amputee

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

Residual limb health and comfort of any person with limb loss of all levels is crucial to achieving maximum prosthetic use and function. There is currently inadequate data substantiating the impact of interface design on socket comfort, residual limb health and function. There are two alternative interface designs for the military and veteran above knee amputee that could provide answers to issues germane to above knee amputees such as moisture control, skin temperature and condition. The Dynamic Socket (DS) design is comprised of a flexible interface and minimal laminated rigid frame to reduce thermal layers, increase flexibility and comfort while retaining ischial containment. In contrast, a Sub-I design has significantly lower trim lines, without ischial containment compared with a traditional interface. However, these alternative designs could compromise overall function compared to the standard of care interface design. Therefore the focus of this clinical trial is to determine if the
DS and Sub-I alternative interface designs will improve socket comfort, residual limb health and function compared to the standard of care IRC interface design.

15. SUBJECT TERMS

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1. INTRODUCTION:

Residual limb health and comfort of any person with limb loss of all levels is crucial to achieving maximum prosthetic use and function. There is currently inadequate data substantiating the impact of interface design on socket comfort, residual limb health and function. There are two alternative interface designs for the military and veteran above knee amputee that could provide answers to issues germane to above knee amputees such as moisture control, skin temperature and condition. The Dynamic Socket (DS) design is comprised of a flexible interface and minimal laminated rigid frame to reduce thermal layers, increase flexibility and comfort while retaining ischial containment. In contrast, a Sub-I design has significantly lower trim lines, without ischial containment compared with a traditional interface. However, these alternative designs could compromise overall function compared to the standard of care interface design. Therefore the focus of this clinical trial is to determine if the DS and Sub-I alternative interface designs will improve socket comfort, residual limb health and function compared to the standard of care IRC interface design.

2. KEYWORDS: Provide a brief list of keywords (limit to 20 words).

prosthetic socket, interface, perspiration, residual limb, comfort, health, vacuum-assisted suspension, brimless

3. ACCOMPLISHMENTS:

What were the major goals of the project?

Primary Aim: To determine if military and veteran transfemoral amputees of non-dysvascular etiology will experience improved residual limb health following accommodation with DS and Sub-I interfaces compared to the standard of care IRC interface. In order to address the primary aim, research question (RQ) #1 was posed:

RQ #1. Compared to the standard of care IRC interface, do DS and Sub-I interfaces decrease:

a. skin temperature?
b. perspiration?
c. vertical interface movement (pistoning)?

Secondary Aim #1: To determine if military and veteran transfemoral amputees of non-dysvascular etiology will demonstrate increased function following accommodation with DS and Sub-I interfaces compared to the standard of care IRC interface. In order to address Secondary Aim #1, RQ #2 was posed:

RQ #2. Compared to the standard of care IRC interface, do DS and Sub-I interfaces improve:

a. balance and stability?
b. mobility?

Secondary Aim #2: To determine if military and veteran transfemoral amputees of non-dysvascular etiology will prefer DS or Sub-I interfaces compared to the standard of care IRC interface, following accommodation. In order to address Secondary Aim #2, RQ #3 was posed:

RQ #3. In the short and long term, compared to the standard of care IRC interface, are DS and Sub-I
interfaces:

a. more comfortable?
b. preferred?

What was accomplished under these goals?

Since the prior annual report, a total of 12 participants were recruited for the study (including signing informed consent). There are an additional 5-6 participants interested in participating. Of the 12 consented participants, 8 completed testing.

Concurrent with data collection, the research team has worked diligently to prepare the collected data for analysis. With sufficient data now collected, preliminary analysis is underway.

What opportunities for training and professional development has the project provided?
A Mechanical Engineering undergraduate student was hired to assist with lab setup, equipment calibration, data collection, and data management and analysis. As part of these duties, the student is learning to interact with human subjects as well as how to manage data and prepare it for analysis. He will continue to assist through analysis and dissemination.

How were the results disseminated to communities of interest?
Nothing to report at this time.

What do you plan to do during the next reporting period to accomplish the goals?
We plan to continue subject recruitment and anticipate being completing data collection during the next reporting period. Additionally, once all data is collected, the research team will focus on data analysis and preliminary preparation for dissemination.

4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project?
Nothing to report at this time.

What was the impact on other disciplines?
Nothing to report at this time.

What was the impact on technology transfer?
Nothing to report at this time.

What was the impact on society beyond science and technology?
Nothing to report at this time.

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change
Subjects were reporting acclimation to experimental sockets at a faster rate than originally anticipated in the grant proposal. Subjects were requesting to test sooner than the protocol allowed. Therefore, the protocol and IRB were amended for subject assessment based on subject self-reported accommodation to the experimental sockets instead of the previously mandated (minimum 10 days) accommodation requirements.

Actual or anticipated problems or delays and actions or plans to resolve them

1. A modification was made to the subject eligibility criteria. The upper end of the age range was increased from 44 to 60 due to slow recruitment. Several potential

participants expressed interest in the study, but could not participate due to the age limit. Since the modification, 2 of those participants signed informed consent.

2. The custom skin temperature measurement tool designed by the team failed during a data collection, resulting in the loss of 1 continuous data set on one socket for one subject. Because this data is logged to a memory card as opposed to presented on screen in real time, this was noticed during data extraction immediately following data collection. Fortunately, a spare measurement tool was made with the original and was used for subsequent data collections as the original was repaired. No further data was lost. The team continues with one primary measurement tool and has a back-up in the event of future failures. The loss of the 1 data set will necessitate an intention to treat analysis as part of the statistical analysis model. This is standard practice in research.

Changes that had a significant impact on expenditures
Nothing to Report

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents
Nothing to Report

6. PRODUCTS:

• Publications, conference papers, and presentations
Journal publications
Nothing to report at this time.

Books or other non-periodical, one-time publications.
Nothing to report at this time.

Other publications, conference papers, and presentations.
The PI presented a status update verbally to Dr. Wolf at MHSRS (August 2017, Kissimmee, FL).

• Website(s) or other Internet site(s)
Nothing to report.

• Technologies or techniques
Nothing to report.

• Inventions, patent applications, and/or licenses
Nothing to report.

• Other Products
Nothing to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?
Name: Jason Highsmith
Project Role: Principal Investigator

Researcher Identifier: N/A
Nearest person month worked: 1 calendar month
Contribution to Project: Coordinated and planned project with the members of the research team. Submitted institutional and DOD IRBs and ClinicalTrials.gov registry. Tested study thermistor with Dr. Lura (see below). Presented a status update at the September 2016 review and analysis meeting for the DOD prosthetic socket portfolio at Fort Detrick, MD

Name: Rebecca Miro
Project Role: Research Coordinator
Researcher Identifier: N/A
Nearest person month worked: 1 calendar month
Contribution to Project: Managed set-up and execution of 4 study subcontracts. Worked with Dr. Highsmith to submit IRB applications and ClinicalTrials.gov registry. Assisted Dr. Highsmith with data collection.

Name: Derek Lura
Project Role: Subcontract PI (Florida Gulf Coast University)
Researcher Identifier: N/A
Nearest person month worked: 0.5 calendar month
Contribution to Project: Designed, built, and tested the thermistor that will be used to record temperature during treadmill walking.

Name: Loi Ho
Project Role: Study Prosthetist
Researcher Identifier: N/A
Nearest person month worked: 2 person months
Contribution to Project: As the study prosthetist, Ms. Ho measured, cast, fabricated and fit sockets for enrolled subjects.

Name: Stephanie Carey
Project Role: Collaborator, Mechanical Engineering
Researcher Identifier: N/A
Nearest person months worked: 0.6 cal months
Contribution to project: Collaboration with research team regarding preliminary data analysis. Mentoring undergraduate student.

Name: Michael Porter
Project Role: Undergraduate student, Mechanical Engineering
Research Identifier: N/A
Nearest person months worked: 0.6 calendar months
Contribution to project: De-identifying and processing data from various outcome measures. Preparing all study data for processing and preliminary data analysis. Literature searches.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

No.

What other organizations were involved as partners?

Organization Name: Florida Gulf Coast University
Location: Fort Myers, FL
Financial Support: None
In-Kind Support: None
Facilities: None
Collaboration: None
Personnel Exchanges: None

Organization Name: Prosthetic Design & Research
Location: Tampa, FL
Financial Support: None
In-Kind Support: None
Facilities: None
Collaboration: None
Personnel Exchanges: None

Organization Name: Tampa VA Research & Education Foundation
Location: Tampa, FL
Financial Support: None
In-Kind Support: None
Facilities: None
Collaboration: None
Personnel Exchanges: None

8. SPECIAL REPORTING REQUIREMENTS: None

9. APPENDICES: Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and